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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,916	08/13/2002	Robert Gerard Ankenbauer	DAVII48.001APC	6713

20995 7590 05/17/2004

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,916

Applicant(s)

ANKENBAUER ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8, 10, 11, 13, 14, 17-23 and 25-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-4, 6-8, 10-11, 13-14, 17-23, 25-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restriction

1. The amendments filed on 11/13/01, 3/19/02 and 8/13/02 have been entered.

Status of claims

2. Claims 5, 9, 12, 15, 16, and 24 have been canceled.

Claim 49 has been entered.

Claims 1-4, 6-8, 10-11, 13-14, 17-23, 25-49 have been amended.

Claims 1-4, 6-8, 10-11, 13-14, 17-23, 25-49 are pending in the application.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, 6-8, 10-11, 13-14, 17-20, 21-23, 25-26 and 49 drawn to an isolated or recombinant immunogenic polypeptide comprising the Lawsonia SodC polypeptide, variant or truncated variant thereof, a vaccine composition comprising SEQ.ID.NO: 1 or the amino acid sequence encoded by pALK14 (see Para # 5).

Group II claims 28-30 and 37-42, 46 and 47 drawn to a vaccine vector, polynucleotide that encodes the immunogenic polypeptide SEQ.ID.NO: 1 or polynucleotide, SEQ.ID.NO: 2 or Plasmid pALK 14 or Plasmid pALK 13 (see Para # 5).

Group III, claims 31-33 drawn to an antibody that binds to SEQ.ID.NO: 1 or the amino acid sequence encoded by pALK14 (see Para # 5).

Group IV claims 27 and 48 drawn to a combination vaccine composition comprising the first component comprising the amino acid sequence set forth in SEQ.ID.NO: 1 or the amino

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acid sequence encoded by pALK14 (ATCC207155) and a second immunogenic component comprising OmpH, FigE, hemolysin and autolysin. (see Para # 5).

Group V, claims 34-35 drawn to a method for diagnosing *Lawsonia intracellularis* using antibody that binds to SEQ.ID.NO: 1 or the amino acid sequence encoded by pALK14 (see Para # 5).

Group VI, claim 36 drawn to a method of identifying a previous or current infection of *Lawsonia intracellularis* using an immunogenic polypeptide, SEQ.ID.NO: 1 or the amino acid sequence encoded by pALK14 (ATCC207155)(see Para # 5).

Group VII, claims 43-45 drawn to a method for identifying *Lawsonia intracellularis* in a sample using DNA polynucleotide that encodes the immunogenic polypeptide SEQ.ID.NO: 1 or polynucleotide, SEQ.ID.NO: 2 or Plasmid pALK 14 or Plasmid pALK 13 (see Para # 5).

4. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of linking groups appears to be that they are all related to peptides, nucleic acids and antibodies and methods using said peptides, nucleic acids and antibodies. However, Panaccio et al 1997 disclose an isolated polypeptide or recombinant polypeptide comprising *Lawsonia* variant (see claims) and thus read on the variants of claimed invention. Various proteins recognized by western blots read on variant that mimics T-cell or B-cell epitopes of *Lawsonia*. These proteins were reacted to antibodies obtained from vaccinated sera (see example 14) indicating that these are immunogenic polypeptides. Therefore, no special technical feature exists for Group I as defined by PCT Rule 13.2, because it does not define a

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contribution over the prior art. Therefore, it does not constitute a special technical feature by definition and hence unity of invention is lacking.

The special technical feature of Group I is considered to be polypeptide, which is made up of amino acids.

The special technical feature of Group II is considered to be polynucleotide that shares no common structure, property and function with Group I since peptides contain amino acids and do not share the same or a corresponding technical feature with Group II, DNA.

The special technical feature of Group III considered to be antibody that shares no common structure, property and function from Inventions I-II since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing and do not require each other for their practice.

Since the special technical feature of the Group I invention is not present in the Group II-III claims, and the special technical features of the Group II-III inventions are not present in the Group I claims, unity of invention is lacking.

The technical feature linking Groups IV-VII is considered to be a combination vaccine comprising more than one recombinant peptide in group IV that share no common structure with group I as it contains various components and methods as groups V-VII utilizing products that share no common structure, property and function and methods of using products so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among groups IV-VII.

Accordingly, Groups I-VII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

DISTINCT INVENTIONS

5. For each group of inventions I-VII above, restriction to one of the following invention is also required under 35 U.S.C. 121 and 372 as it is not clear that the nucleotide sequence pALK14 has more than one coding sequence and encodes more than one polypeptide.

The election is required to one of the groups I-VII and one of the inventions from the following:

Polypeptide comprising SEQ ID NO: 1,

The amino acid sequence encoded by the nucleotide sequence pALK14,

Plasmid pALK14,

Plasmid pALK 13,

And nucleic acid SEQ.ID.NO: 2.

Inventions Polypeptide comprising SEQ ID NO: 1, the amino acid sequence encoded by the nucleotide sequence pALK14, plasmid pALK14, plasmid pALK 13 and SEQ.ID.NO: 2 are not linked so as to form a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claimed peptide SEQ ID NO: 1, the amino acid sequence encoded by the nucleotide sequence pALK14 and the nucleic acid molecule SEQ.ID.NO: 2, plasmid pALK14, plasmid pALK 13 share no common special technical feature because the peptides and nucleic acid molecules have no common structure (i.e., no common sequence), property and function.

Peptide SEQ ID NO: 1, the amino acid sequence encoded by the nucleotide sequence pALK14, plasmid pALK14, plasmid pALK14 and nucleic acid molecules SEQ.ID.NO: 2 represent sequences that share no common structure as polypeptides and the polynucleotides encoding them are not linked by the same or a corresponding special technical feature as to form a single

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form a single general inventive concept. Therefore, where structural identity is required, such as for hybridization or expression of protein or binding of antibody, each sequence appears perform a different function in that peptides elicit an antibody response and nucleic acids encode peptides that specifically bind to an antibody. Thus they share no common structure and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among groups SEQ.ID.NOS.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed Invention from SEQ ID NO: 1, the amino acid sequence encoded by the nucleotide sequence pALK14, plasmid pALK14, plasmid pALK14 and SEQ.ID.NO: 2 from any group elected.

Applicant is advised to point to the examiner if SEQ ID NO: 1 and the amino acid sequence encoded by the nucleotide sequence pALK14 are same. Similarly, applicant is advised to clarify the polynucleotide sequence from plasmid pALK14 , plasmid pALK13 and the polynucleotide sequence SEQ.ID.NO: 2 are the same sequences or different because the claims are not clear on the record. The examiner is considering that the plasmid contains more than nucleic acid sequence. Therefore, clarification is required.

If applicant elects group IV, applicant should elect one first immunogenic component as stated above and in addition one second immunogenic component from OmpH, FigE, hemolysin and autolysin.

6. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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7. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

8 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

5/10/04


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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